Clinical Evidence for the Swedish Adjustable Gastric Band (SAGB)

12th AHWP Meeting – October 25, 2007
Chengdu, China

Ken Sumner, Ph.D.
Vice President, Clinical & Regulatory Affairs

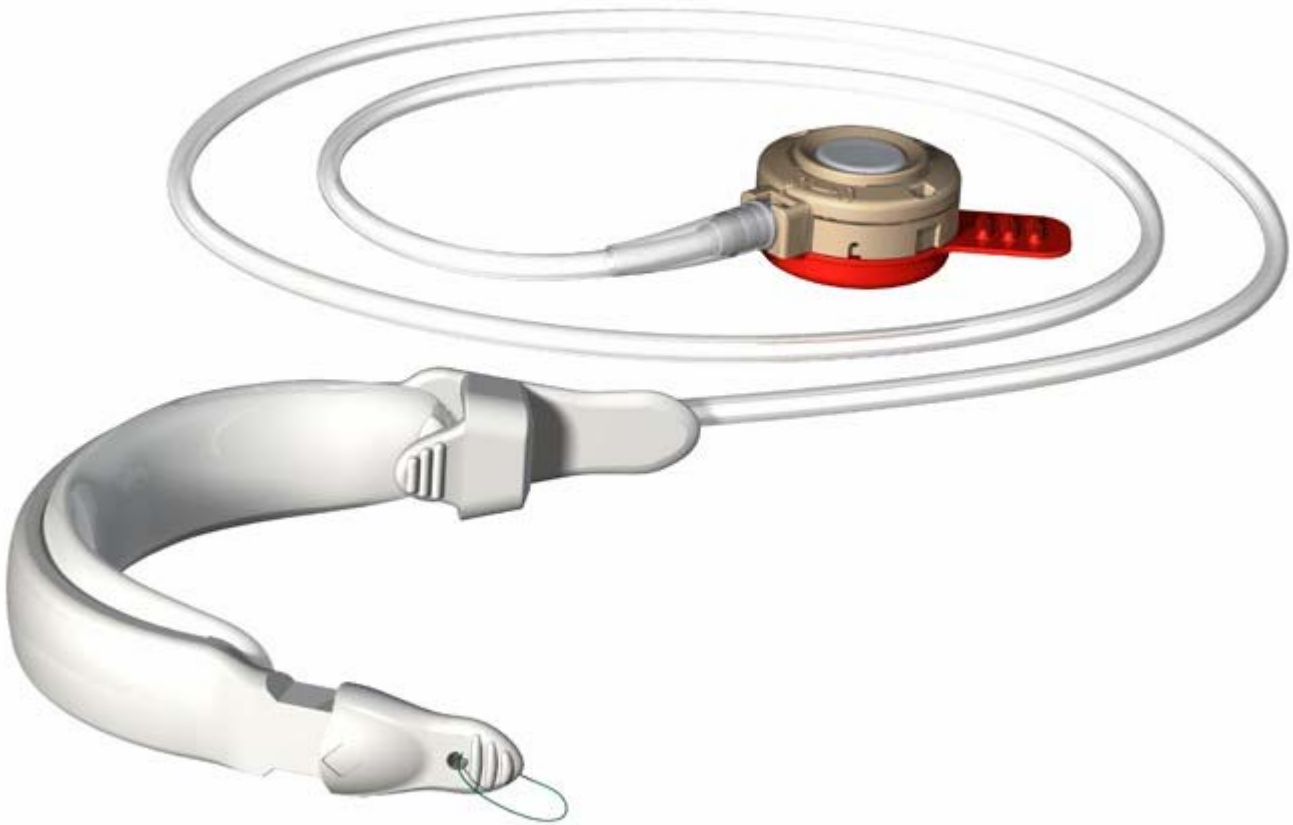
Clinical Evidence

- **Clinical Evidence – The clinical data and the clinical evaluation report pertaining to a medical device.**

- **Clinical Data – Safety and/or performance information that are generated from the clinical use of a medical device.**

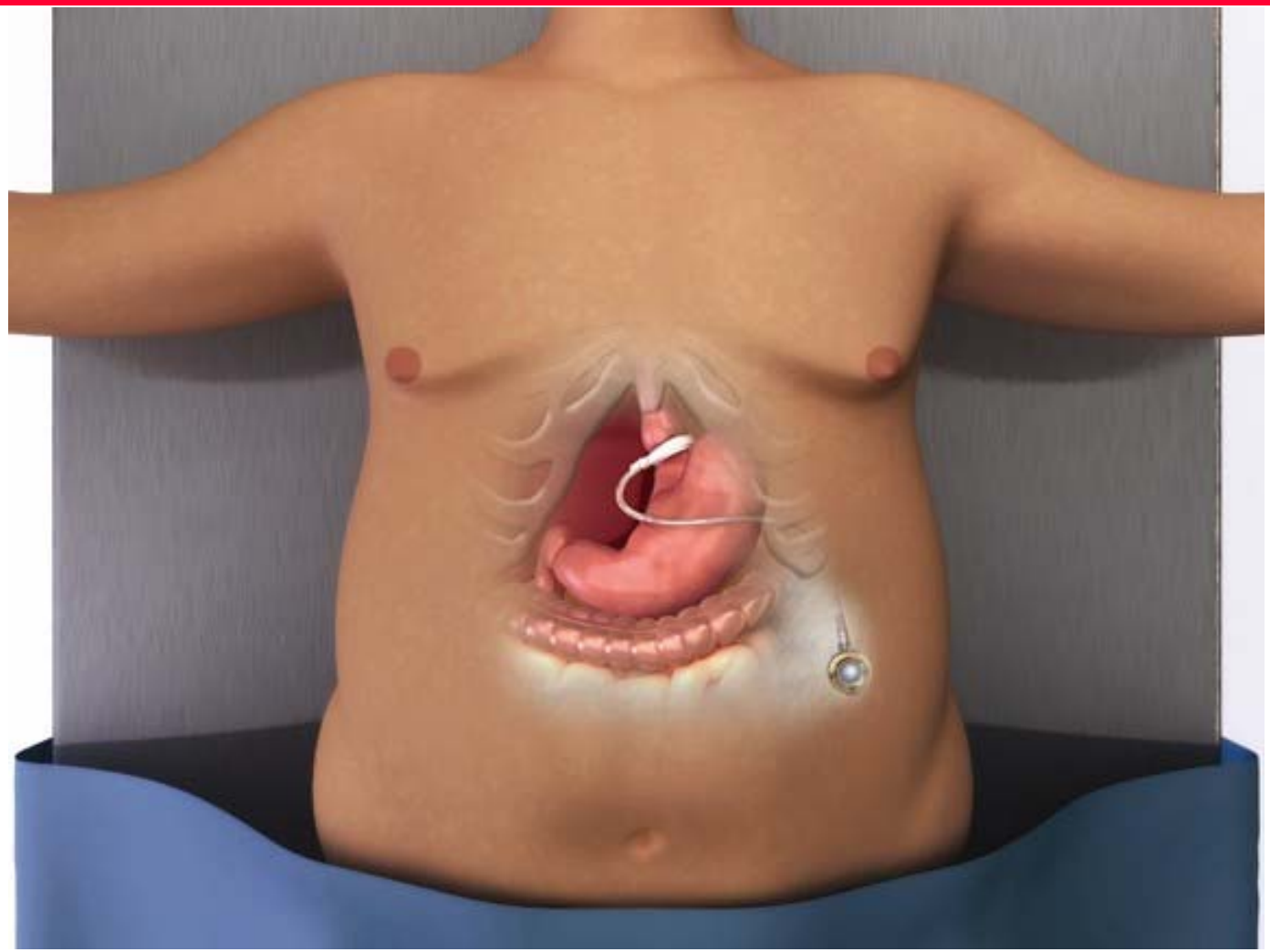
- **Clinical Evaluation – The assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer.**

Swedish Adjustable Gastric Band



ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

Swedish Adjustable Gastric Band



Swedish Adjustable Gastric Band

- **Developed in Sweden**
- **First introduced in Europe in 1996 by Obtech, Inc.**
- **Classified as Class II B**
- **CE mark in 1998**
- **No large-scale clinical investigation, but used published clinical data from similar products**

SAGB Commercialized in Europe

Essential Principles of Safety and Performance (SG1/N41R9:2005)

- ¶ 5.17 – Performance evaluation including, where appropriate, clinical evaluation

Clinical Evaluation – review of relevant scientific literature and/or the review and assessment of data collected through clinical investigation.

SAGB – literature for clinical data from other gastric bands, and data from small studies and pre-clinical (animal) data were sufficient

Gastric Banding in the U.S.

- **All gastric bands placed in Class III (highest risk)**
- **Lap Band® approved in U.S. in 2001 after 3-year clinical investigation**
- **Ethicon Endo-Surgery acquired Obtech in 2002 and was required to perform a similar study**
- **The fact that the product had the CE Mark, clinical literature and product experience in Europe was not acceptable to FDA**

Clinical Evidence

- **Is it a reasonable expectation that the clinical evidence as determined in the EU as sufficient for the CE Mark be accepted by other countries regulatory systems?**

Why Clinical Study in the U.S. when Clinical Evidence available?

- **Regulatory Requirement – Class III devices require clinical evidence including a clinical study. Clinical data in Europe collected retrospectively.**

- **Diet and additional health professionals involved (nutritionist, psychologist) that may treat obesity in a different way in the U.S. (i.e. standard of care)**

Device Classification

European Classification System:

I IIa IIb* III

Scientific Literature is Acceptable

U.S. FDA Classification:

I II III *

Prospective Clinical Study Required

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

* Classification of Gastric Band

Pre-Market Approval Application

A multi-volume submission consisting of all design, pre-clinical, clinical evidence, manufacturing and labeling information.

The clinical information is the equivalent of that in a clinical evaluation to support the product's safety and efficacy.

U.S. Clinical Study

- **Hypothesis driven, 3-year, prospective, single-arm, controlled study, 12 clinical sites.**
- **276 subjects – morbidly obese**
- **Weight loss at 3-years was primary variable, as was rate of device related adverse events**
- **Secondary objectives were Quality of Life and clinical chemistry**
- **Carried out under Good Clinical Practices: ICH Topic E6 (R1) and FDA's CFR 812**

Clinical Studies Outside U.S.

Current Process:

- **Evaluate product in relationship to Essential Principles of Safety and Performance of Medical Devices (SG1/N41R9:2005)**
- **Review documents of GHTF Study Group 5 regarding clinical evaluations and clinical evidence**
- **Clinical investigations are conducted as given in ISO 14155:2003 - Clinical Investigation of Medical Devices for Human Subjects (Parts 1 and 2)**

Clinical Strategy Development

- **Clinical Studies performed to meet needs of regulatory bodies, payers, patients and health professionals**
- **Differences between the U.S. and other countries as to when a prospective clinical study may be required for regulatory clearance**
- **The Good Clinical Practices guidelines and ISO 14155 are the standard guiding principles for how well-controlled clinical studies are carried out**
- **Clinical data from trials is only the beginning of understanding a product's benefit/risk profile.**

Conclusion

- **Harmonization will not lead to one interpretation of terminology.**
- **Each country will take steps to protect its citizens from unsafe products.**
- **The most constructive approach for industry is to: Understand and Respect the point of view of the regulators.**